

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Buehler et al.

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Appln. No.: 10/674,702

Art Unit: 1617

Filed : September 30, 2003

Examiner: Layla Soroush

For : STABLE SUSPENSIONS FOR MEDICINAL DOSAGES

I hereby certify that this correspondence is being transmitted via
The Office electronic filing system in accordance with 37 CFR 1.6(a)(4)

July 14, 2009

(Date of Transmission)

Judith Ubry

(Name)

/Judith Ubry/

(Signature)

July 14, 2009

(Date of Signature)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132 OF GAIL BUEHLER

Dear Sir:

I, Gail Buehler, declare and state that:

1. I am a citizen of the United States, residing at 1102 Quinard Court, Ambler, PA.
2. I have a B.S. in Chemistry from Cedar Crest College.
3. I am a co-inventor of the above-referenced patent application.

4. I have been employed by McNeil Consumer Healthcare Division of McNeil – PPC, Inc. for twenty (20) years. I am presently a Principal Scientist.

5. I have, or others reporting to me, manufactured and tested four loratadine containing suspensions containing different levels of the nucleation inhibitor polyvinylpyrrolidone (PVP) in order to determine the effect of crystal growth over time when the suspension stored at 40 C. Microscopic evaluation of the samples revealed that suspensions with either no PVP as well as those with 1.25%, by weight of the formulation, PVP displayed enlarged crystals of loratadine and the formation of crystal spirolytes of loratadine. However, the suspensions that were prepared with PVP at levels of 2.5% and 5%, by weight of the formulation, surprisingly showed no elongated crystal needles of loratadine, demonstrating the inhibition of crystal growth upon storage. Crystalline growth of the active agent is not preferred in suspensions because of the potential formation of inactive polymorphs of the active and the possible loss of bioavailability of the active agent because of the growth in size of the crystals.

6. I, Gail Buehler, further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further declare that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 35 USC §1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or patent issuing thereon.

By: 
Gail Buehler